INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR NEW PROTOCOL APPROVAL

Date Rec'd in HSO _____

Instructions: Use this form when submitting new protocols to the IRB. Please submit this form electronically along with the protocol and any supporting documents to your CIO designated staff official. However, if submitting hardcopies, please send the original and three copies of all documents to the CIO designated staff official. Consecutively number **ALL** pages, beginning with the title page of the protocol, followed by any consent form(s) and ancillary documents. Complete all applicable items or the form will be returned.

Date Submitted by Investigator: _____

PROTOCOL NO. _____
(For Human Subjects Office Use)

Title of Protocol: _____

Proposed Dates for Project - Begin: _____ End: _____

Name of CDC Employee Serving as Principal Investigator (PI) and Degrees:

_____

9 Check if PI has changed

Scientific Ethics Verification No.: _____ Telephone: _____ Fax: _____

CIO: _____ **Division**: _____ **MS**: _____ Email Address: _____

Names of Other CDC Employee Co-investigators (use supplemental page if > than 3):

1. _____ *Scientific Ethics* Verification No.: _____

2. _____ *Scientific Ethics* Verification No.: _____

3. _____ *Scientific Ethics* Verification No.: _____

STUDY POPULATION (If an international study, provide race/ethnicity of subjects by estimated percentages):

_____

Estimated Number of Subjects: _____

Gender Distribution:
_____ % Female
_____ % Male

Race/Ethnicity Distribution for Domestic Studies:
_____ % American Indian or Alaskan Native
_____ % Asian or Pacific Islander:
_____ % Black or African American; not of Hispanic Origin
_____ % Hispanic
_____ % White, not of Hispanic Origin

Vulnerable Populations

Do the subjects include: _____ YES _____ NO (If **YES**, check all that apply):

_____ Pregnant women and/or fetuses as SPECIFIC targets group (Ref: 45CFR46, Subpart B)

_____ Prisoners (Ref: 45CFR46, Subpart C)

_____ Children 17 years of age or younger (Ref: 45CFR46, Subpart D)
_____ If YES, are you requesting a waiver of parental permission?

_____ Mentally disabled

_____ Economically or educationally disadvantaged

STUDY DESIGN ISSUES (check all that apply):

_____ Will CDC investigators have personal identifiers?

_____ Is a waiver or alteration of informed consent being requested for this project? (Ref:45CFR46.116)

_____ Is a waiver of documentation of consent being requested for this project? (Ref: 45CFR46.117)

_____ If specimens are collected, will they be stored for future use?

_____ Is HIV testing being performed as part of the study?

_____ Is genetic testing planned now or in the future?

_____ Does the study involve the use of a drug or device? (See FDA Regulations)
_____ If YES, will the study be carried out under an Investigational New Drug (IND) or device (IDE)?

FUNDING (check one):

_____ PGO Funding Mechanism Used:

_____ Cooperative Agreement No(s).: _____

_____ Contract No(s).: _____

_____ Grant: _____

_____ Purchase Order (a.k.a. Simplified Acquisition): _____

_____ Other funding mechanism:

_____ Memorandum of Understanding (MOU) (With whom): _____

_____ Interagency Agreement (IAA) (Name of other agency): _____

_____ Other (Specify type and with whom): _____

_____ Only CDC investigators performing study

_____ Collaborative (Non-CDC Investigators & CDC investigators; no funding involved)

LOCATION OF THIS RESEARCH (Use additional sheets if necessary)

_____ U.S. or its territories? _____ Foreign country (countries)?

List All Collaborating Sites by Full Name and Location (include state):	**OPRR Assurance No.:**
1.	
2.	

3.	
4.	
5.	
6.	
7.	

DATA CONFIDENTIALITY INFORMATION (CIRCLE)					**REFERENCES:**
Does CDC have an Assurance of Confidentiality to cover this project?	YES	NO	Applied For	N/A	§ 308(d) PHS Act
Does the local site(s) have a Certificate of Confidentiality to cover this project?	YES	NO	Applied For	N/A	§301(d) PHS Act

Approvals (Signature and Position Title): Branch Chief:	**Date:**	**Remarks:**
Division Director:		
CIO Human Subjects Contact:		